UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EDWARD PENA, individually and on behalf of others similarly situated,

Plaintiff,

v.

INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M.D., a Medical Corporation, and Dr. James ELIST,

Defendants.

Case No. 2:22-cv-03391-SSS-PLAx

ORDER GRANTING IN PART DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT [DKT. 31] AND DENYING DEFENDANTS' REQUEST FOR JUDICIAL NOTICE [DKT. 32]

Before the Court is Defendants International Medical Devices, Inc., Menova International, Inc., Gesiva Medical, LLC, James. J. Elist M.D., A Medical Corporation, and Dr. James Elist's (collectively, "Defendants") Motion to Dismiss the First Amended Class Action Complaint ("FAC"). [Dkt. 31], and Defendants' Request for Judicial Notice in Support of their Motion to Dismiss [Dkt. 32]. For the reasons below, Defendants' Motion to Dismiss is **GRANTED IN PART** and Defendants' Request for Judicial Notice is **DENIED**.

I. BACKGROUND

This is a diversity class action regarding the advertisement of Penuma, a penile implant device and procedure. Plaintiff Edward Peña alleges that Defendants falsely advertised and misled consumers regarding the safety and efficacy of the Penuma device and procedure in violation of California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 ("FAL"), California's Consumers Legal Remedies Act, Cal. Civ. Code § 1750 *et seq.* ("CLRA"), and California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 *et seq.* ("UCL").

II. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Dismissal under Rule 12(b)(6) is proper only when a complaint exhibits either a "lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dept.,* 901 F.2d 696, 699 (9th Cir. 1988). In reviewing a motion to dismiss under Rule 12(b)(6), the Court must assume the truth of all factual allegations and must

construe all inferences from them in the light most favorable to the nonmoving party. *Thompson v. Davis*, 295 F.3d 890, 895 (9th Cir. 2002); *Cahill v. Liberty Mut. Ins. Co.,* 80 F.3d 336, 337-38 (9th Cir. 1996). "It is axiomatic that the motion to dismiss . . . is viewed with disfavor and is rarely granted." *Ernst & Haas Mgmt. Co., Inc. v. Hiscox, Inc.*, 23 F.4th 1195, 1199 (9th Cir. 2022) (citation omitted).

When an action alleges fraud, Rule 9(b) imposes additional pleading requirements. A plaintiff alleging fraud "must state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). This requirement means that the plaintiff must identify the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (citations omitted). "[A]llegations of fraud must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged 'so that they can defend against the charge and not just deny that they have done anything wrong.'" *Sanford v. MemberWorks, Inc.*, 625 F.3d 550, 558 (9th Cir. 2010) (citation omitted).

III. DISCUSSION

A. Rule 9(b)

Defendants argue the FAC fails to plead with particularity as Federal Rule of Civil Procedure Rule 9(b) requires. Pursuant to Rule 9(b), "a pleading must identify the who, what, when, where, and how of the misconduct charged, as well as what is false or misleading about the purportedly fraudulent statement, and why it is false." *Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1019 (9th Cir. 2020) (citation omitted).

Defendants claim Peña does not identify any particular advertisements he read and relied upon on Dr. Elist's website, when he read them, or how he was misled. [Dkt. 31 at 19]. Defendants are wrong. Peña identified he read the

advertisements before his appointment with Dr. Elist in October of 2020 [Dkt. 16 ¶¶ 22, 26], included a screenshot of the advertisement [*Id.* ¶ 49], and explained that the statement "Enhance and enlarge the length, girth, and size of your penis," is misleading because Penuma "is not effective to enhance the appearance of normal penises." [*Id.* ¶ 52]. Moreover, Defendants have even gone so far as to acknowledge which pages from Dr. Elist's clinic website are "potentially relevant," which according to Defendants are Figures 4, 5, and 7 in paragraph 51 of the complaint. [Dkt. 31 at 21]. Thus, "[Peña] ha[s] pleaded sufficient detail to put Defendants on notice[.]" *Moore*, 966 F.3d at 1020.

B. Shotgun Pleading

Defendants also argue the FAC constitutes an impermissible shotgun pleading that "uses the omnibus term 'Defendants' throughout a complaint by grouping defendants together without identifying what the particular defendants specifically did wrong." *Morris v. Sun Pharma Glob. Inc.*, No. CV2010441, 2021 WL 3913191, at *3 (C.D. Cal. May 13, 2021) (citation omitted). "Rule 9(b) 'does not allow a complaint to . . . lump multiple defendants together but require[s] plaintiffs to differentiate their allegations when suing more than one defendant.'" *Destfino v. Reiswig*, 630 F.3d 952, 958 (9th Cir. 2011) (citation omitted).

The FAC does not constitute a shotgun pleading and does not violate Rule 9(b) because Peña sufficiently alleges each Defendants' role in the alleged wrongdoing. First, Plaintiff has specified which false and misleading advertisements were made on Dr. Elist's website, IMD's Penuma website, and Gesiva's website and social media. [Dkt. 16 ¶¶ 49–51]. Second, Peña has detailed each Defendants' role in the alleged joint enterprise: Peña specifies that IMD is responsible for manufacturing and selling the Penuma device, as well as applying for Penuma's FDA's clearances [Dkt. 16 ¶¶ 42–43, 60], that Menova owns the intellectual property associated with Penuma [*id.* ¶¶ 34–35],

that Dr. Elist invented the Penuma device, created and controlled IMD and Menova, and performs Penuma surgeries [*id.* ¶¶ 31–34, 61], and that Gesiva distributes the Penuma device to surgeons around the United States [*id.* ¶ 35].

Defendants also argue Peña has not sufficiently pled a joint enterprise among Defendants. "To establish a joint venture under California law, Plaintiffs must show 'an agreement between the parties under which they have a community of interest, that is, a joint interest, in a common business undertaking, an understanding as to the sharing of profits and losses, and a right of joint control.'" *Ratha v. Phatthana Seafood Co.*, 35 F.4th 1159, 1173 (9th Cir. 2022), *cert. denied*, No. 22-411, 2022 WL 17408202 (U.S. Dec. 5, 2022). However, "[w]hile in a technical joint venture there is usually a sharing of profits and losses in prosecution of the common enterprise, the mode of participation in the fruits of the undertaking may be left to the agreement of parties; and whether they create the strict relation of joint adventurers or some other relation involving cooperative effort depends on their actual intention." *Krantz v. BT Visual Images, L.L.C.*, 89 Cal. App. 4th 164, 177–78 (2001), *as modified* (May 22, 2001). Although "whether actors entered into a joint enterprise is question of fact," *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1023 (Fed. Cir. 2015), the question here is whether Peña's allegations are sufficient to state a claim.

Peña has sufficiently pled a joint enterprise among Defendants. Plaintiff has pled that each Defendant "agreed to market Penuma for the cosmetic enlargement of normal penises" [Dkt. 16 ¶ 17], that Dr. Elist, sued both as an individual and as his own Medical Corporation, owns 100% of Defendants IMD and Menova, meaning that Dr. Elist, IMD, and Menova share 100% of profits and losses and that IMD and Menova are subject to joint control by Dr. Elist [*id.* ¶¶ 33–34], that Dr. Elist's son, Jonathan Elist, is IMD's chief executive officer and registered agent, and IMD shares his address [*id.* ¶¶ 6, 33], that Dr. Elist

himself is the registered agent for Menova and shares its address [Dkt. 16 ¶ 7], and that Gesiva also entered into Defendants' joint agreement to market Penuma for the cosmetic enlargement of normal penises and acted as part of the joint enterprise" [*id.* ¶ 18]. Plaintiff has also directly quoted language from Gesiva's website, as well reproducing a promotional Twitter post by Gesiva, in which Gesiva uses the same allegedly misleading language as appears on Dr. Elist's website and on IMD's Penuma website. [*Id.* ¶¶ 50, 51 at 14]. At the motion to dismiss stage, taking these factual allegations as true and viewing them in the light most favorable to Peña, Peña's allegations regarding joint enterprise and each Defendants' role therein are sufficient to state a claim.[1]

C. Actionable Misrepresentation

Defendants argue the FAC fails to allege an actionable misrepresentation by Defendants. But Defendants' arguments are factual disputes rather than disputes regarding the sufficiency of Peña's factual allegations. Factual disputes are not proper argument for a motion to dismiss. The question at the motion to dismiss stage is whether Peña has pled factual allegations that when taken as true and viewed in the light most favorable to Peña are sufficient to state a claim for relief that is plausible on its face. *Iqbal*, 556 U.S. at 678.

First, Defendants argue Dr. Elist's clinic website is not false or misleading. But Peña has sufficiently pled that Dr. Elist's clinic website is false or misleading. Peña alleges Dr. Elist's website encourages consumers to

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[1] Defendants argue that the claims against Menova fail because "the FAC does not allege that Menova had anything to do with the representations made in the Penuma advertising." [Dkt. 31 at 30]. However, "where two or more actors form a joint enterprise, all can be charged with the acts of the other, rendering each liable for the steps performed by the other as if each is a single actor." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1023 (Fed. Cir. 2015) (citing Restatement (Second) of Torts § 491 cmt. b). Because Peña has successfully pled a joint enterprise that includes Menova, the alleged actions of the other Defendants apply also to Menova.

"[e]nhance and enlarge the length, girth, and size of your penis," and touted that Penuma "[l]ooks, feels, and functions just like nature intended – just significantly large." [Dkt. 16 ¶ 49]. Peña also alleges Dr. Elist's website deliberately misquoted the intended purpose from Penuma's FDA 510k clearance to present a false impression that the FDA had determined that Penuma was safe and effective for cosmetic penile enlargement, marketing it as "the first FDA-cleared penile implant for cosmetic enhancement" and "the first FDA-cleared penile implant for enhancement." [*Id.* ¶ 49–51]. However, as Peña alleges, "Penuma does not increase the length of patients' flaccid penises, but causes disfigurement and scarring that often leads to a shortening of the erect penis in the majority of cases," and that "[t]he scarring interferes with normal penis function by reducing sensation in the penis, leading to sexual dysfunction." [*Id.* ¶ 62]. Taking these allegations as true and in the light most favorable to Peña, Peña has sufficiently pled that Dr. Elist's clinic website is false or misleading.

Second, Defendants argue Peña lacks factual support for his claims that the Penuma is not safe or effective, specifically that Peña has not provided facts to support his allegations. But at the motion to dismiss stage, factual allegations are taken as true, *Iqbal*, 556 U.S. at 678, and Peña need not actually prove every factual allegation in the complaint because that task is better left for after discovery has been conducted.

Here, the FAC sufficiently alleges the Penuma is not safe or effective. As Defendants note, Peña alleges that "[t]here is no evidence that the Penuma device makes patients' non-erect penises longer, [Dkt. 16 ¶ 36], that the procedure "often results in abnormal and deformed-looking penises" [*id.* ¶ 25], that the Penuma device "frequently causes complications that require the implant to be removed" [*id.* ¶ 52], that the procedure "frequently causes scarring, resulting in the penis becoming shorter" [*id.* ¶ 53], that "many patients

experience sexual dysfunction, including loss of sensation, as a consequence of the receiving the Penuma implant" [*id.* ¶ 56], and that the procedure "also frequently causes painful infections that lead to yet more scarring" [*id.* ¶ 63]. These allegations, when taken as true and viewed in the light most favorable to Peña, suffice to state a claim. To the extent Defendants seek documents, articles, or scientific studies to substantiate these factual allegations, that is a task for discovery, not a plaintiff's complaint.

Third, Defendants also argue that the statement that Penuma was "the first FDA-cleared penile implant for cosmetic enhancement" is not false or misleading. But again, Defendants raise a factual dispute, which is not ripe for a motion to dismiss. The question here is whether the FAC sufficiently alleges that the statement regarding FDA clearance was false or misleading. It does.

Peña alleges the drelist.com and penuma.com websites, as well as Gesiva's website and social media, deliberately misquoted the intended purpose from Penuma's FDA 510k clearance to present a false impression that the FDA had determined that Penuma was safe and effective for cosmetic penile enlargement, marketing it as "the first FDA-cleared penile implant for cosmetic enhancement" and "the first FDA-cleared penile implant for enhancement." [*Id.* ¶¶ 49–51]. Peña also alleges that he was misled, as a reasonable consumer would be, when he reasonably believed and concluded that Penuma was safe, effective, and FDA-approved for men with normal, healthy penises who wanted to increase the size of their penises for aesthetic reasons. [*Id.* ¶¶ 23–25, 48, 52, 58, 82, 98, 113]. Thus, the FAC sufficiently pleads that Defendants' statement regarding FDA clearance is false or misleading.

D. Actionable Omission

Defendants also argue Peña has failed to plead an actionable omission. An omission is actionable under the CLRA if the omitted fact is (1) "contrary to a [material] representation actually made by the defendant" or (2) is "a fact the

defendant was obliged to disclose." *Gutierrez v. Carmax Auto Superstores California*, 248 Cal. Rptr. 3d 61, 84 (Cal. Ct. App. 2018). "There are 'four circumstances in which nondisclosure or concealment may constitute actionable fraud: (1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material facts." *LiMandri v. Judkins*, 60 Cal. Rptr. 2d 539, 543 (Cal. Ct. App. 1997) (citing *Heliotis v. Schuman*, 226 Cal. Rptr. 509, 512 (Cal. Ct. App. 1986)). "[I]n order for non-disclosed information to be material, a plaintiff must show that 'had the omitted information been disclosed, one would have been aware of it and behaved differently.'" *Keegan v. Am. Honda Motor Co.*, 838 F. Supp. 2d 929, 939 (C.D. Cal. 2012) (citing *Oestreicher v. Alienware Corp.*, 544 F. Supp. 2d 964, 971 (N.D. Cal. 2008)).

Here, Peña has alleged that "Defendants had a duty to Plaintiff and the Class members to disclose the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared because: (a) Defendants were in a superior position to know the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared; (b) Plaintiff and the Class members could not reasonably have been expected to know the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared; and (c) Defendants knew that Plaintiff and the Class members could not reasonably have been expected to know the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared." [Dkt. 16 ¶ 96]. Thus, taking Peña's allegations as true and construing them in the light most favorable to him, Defendants had a duty to disclose based on partial representations and suppression of some material facts. Defendants advertised that Penuma was

"FDA cleared" and that it would "enlarge the length, girth, and size of your penis," while omitting material facts including the high rates of complications and the fact that Penuma's "FDA clearance" was only for "cosmetic correction of soft tissue deformities" and did not denote the limits or specific scope of the FDA's actual official approval for the device. [*Id.* ¶¶ 37, 48]. These omissions are material, according to Peña's allegations, because if he and other reasonable consumers had known these facts, they would not have purchased the Penuma device and procedure. [*Id.* ¶¶ 23–25, 98]. Peña has thus sufficiently pled an actionable omission.

E. Unlawful or Unfair Practices under the UCL

Defendants argue Peña has failed to allege a violation of the UCL because he has not alleged any actionable misrepresentation or omission and therefore has not alleged a violation of the FAL or CLRA. The UCL prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. The UCL is "sweeping, embracing 'anything that can properly be called a business practice and that at the same time is forbidden by law." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999) (internal quotations omitted). As discussed above, Peña has plausibly alleged actionable misrepresentations and omissions by Defendants and has therefore alleged violations of the FAL and CLRA, and therefore unlawful and unfair practices under the UCL.

Defendants also argue that Peña failed to state a UCL claim for violation of the California Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"), Cal. Health & Safety Code §§ 109875 *et seq.* The Sherman Law provides "[i]t is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular." Cal. Health & Safety Code § 110390. Defendants claim that Peña has failed to state a Sherman Law claim based on

the same reasons it believes Peña did not sufficiently plead a violation of the FAL or CLRA. However, because Peña did sufficiently plead violations of the FAL and CLRA, Defendants' argument here, too, fails.

F. Learned Intermediary Doctrine

Defendants argue that due to the learned intermediary doctrine, IMD, as the manufacturer of the Penuma, and Gesiva, as its distributor, owed no duty to Peña and the claims against them should be dismissed. "[T]he learned intermediary doctrine applies to consumer protection claims predicated on a failure to warn." *Saavedra v. Eli Lilly & Co.*, No. 2:12-CV-9366-SVW-MAN, 2013 WL 3148923, at *3 (C.D. Cal. June 13, 2013). As its name suggests, the learned intermediary doctrine provides that the duty to warn in the case of medical devices or drugs only runs from the device or drug manufacturer to the intermediary physician, and not to the patient. *See Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1144 (S.D. Cal. 2016).

However, based on Peña's allegations, Dr. Elist is not a learned intermediary whose presence absolves IMD and Gesiva of liability. Rather, Dr. Elist is alleged to be the architect of a joint enterprise with IMD and Gesiva, all of whom had a duty to not falsely advertise or mislead consumers, and all of whom allegedly did. Thus, the learned intermediary doctrine does not apply.

G. Equitable Relief

Defendants argue Peña's claims for equitable relief should be dismissed because the FAC does not plead that legal remedies are inadequate. "[T]he necessary prerequisite for a court to award equitable remedies is 'the absence of an adequate remedy at law." *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 842 (9th Cir. 2020) (quoting *Barranco v. 3D Sys. Corp.*, 952 F.3d 1122, 1129 (9th Cir. 2020)).

Here, Peña seeks injunctive and equitable relief [Dkt. 16 ¶ 86], but does not allege an inadequate remedy at law. Peña argues he has pled injunctive

relief, which is necessary to prevent future harm "because if the Penuma device and procedure were redesigned to be safe and effective for cosmetic penile enlargement, FDA-cleared for this use, and truthfully marketed, there is a possibility that Plaintiff and the Class members would purchase a Penuma device and procedure in the future." [*Id.* ¶ 115]. However, in order to have standing to seek injunctive relief, "threatened injury must be certainly impending to constitute injury in fact" and "allegations of possible future injury are not sufficient." *In re Coca-Cola Prod. Mktg. & Sales Pracs. Litig. (No. II)*, No. 20-15742, 2021 WL 3878654, at *2 (9th Cir. Aug. 31, 2021) (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)). Thus, Peña's allegation that there is a "possibility" he and the class members would purchase Penuma device and procedure in the future is insufficient to confer standing to pursue injunctive relief. *See In re Coca-Cola*, 2021 WL 3878654, at *2 ("[P]laintiffs' declarations that they would 'consider' purchasing properly labeled Coke are insufficient to show an actual or imminent threat of future harm."); *Lanovaz v. Twinings N. Am., Inc.*, 726 F. App'x 590, 591 (9th Cir. 2018) ("Lanovaz's statement that she would "consider buying" Twinings products does not satisfy [the 'actual or imminent' injury Article III] standard."). Thus, Peña's claims for equitable relief are **DISMISSED WITHOUT PREJUDICE**.

H. Leave to Amend

Peña seeks leave to amend, and Defendants do not oppose. Under Federal Rule of Civil Procedure 15(a)(2), "[t]he court should freely give leave to amend when justice so requires." Thus, the Court grants Peña leave to amend the FAC with respect to his claims for equitable relief only.

I. Request for Judicial Notice

The Court has reviewed Defendants' request for judicial notice of thirteen documents in support of their motion to dismiss. Judicial notice is

discretionary. *See* Fed. R. Civ. P. 201. None of the documents presented by Defendants are dispositive or necessary to resolve the motion to dismiss because they merely raise factual disputes beyond the scope of the motion to dismiss. The Court thus **DENIES** Defendants' request for judicial notice.

IV. CONCLUSION

Therefore, the Court **GRANTS IN PART** Defendants' Motion to Dismiss and **ORDERS** as follows:

1. Peña's claims for equitable relief are **DISMISSED WITHOUT PREJUDICE**.
2. Defendants' motion to dismiss is otherwise **DENIED**.
3. Defendants' requests for judicial notice are **DENIED**.
4. The Court **GRANTS** Peña's request for leave to amend the FAC with respect to his claims for equitable relief only.
5. Peña is **DIRECTED** to file a second amended complaint by January 20, 2023. Failure to do so may result in dismissal with prejudice of his claims for equitable relief.

IT IS SO ORDERED.

Dated: January 10, 2023

SUNSHINE S. SYKES
United States District Judge